

REMARKS

The office action dated May 23, 2006 (the "Office Action") has been received and carefully noted. Claims 1, 3-20 and 26 were examined. Claims 1, 3-20 and 26 were rejected. Claims 1, 3 and 4 are amended. The claims were amended to comply with 35 U.S.C. § 112. As such, no new matter has been added. Claims 1, 3-20 and 26 remain in the Application.

I. Claims Rejected Under 35 U.S.C. § 112

Claims 3 and 4 were rejected under 35 U.S.C. § 112 as being indefinite for depending on a cancelled claim. Claims 3 and 4 are amended to depend on currently pending claim 1. Applicant respectfully requests that the Examiner withdraw the rejection.

II. Claims Rejected Under 35 U.S.C. § 103

A.

Claims 1, 3, 5-9, 11, 12, 14-20 and 26 were rejected under 35 U.S.C. § 103 (a) as being unpatentable over in view of U.S. Patent No. 6,063,085 to Tay et al. ("*Tay*"), in view of U.S. Patent No. 6,539,792 to Lull, et al. ("*Lull*"). In order to establish a *prima facie* case of obviousness: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference; (2) there must be a reasonable expectation of success; and (3) the references when combined must teach or suggest all of the claim limitations. MPEP 2142. Applicants respectfully submit that a *prima facie* case of obviousness has not been established.

More particularly, none of the cited references either singly or combined provide the suggestion or motivation to modify the references. The mere fact that the references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. MPEP 2143.01. Independent claim 1 is directed to "a needle coupled to a thermally conductive heating element, wherein the heating element is coupled to balanced circuit which measures a first differential resistance between the heating element and a variable resistor in response to a first condition and second differential resistance in response to a second condition to indicate a change of conditions related to a distance of penetration of the heating element into a tissue." Independent claim 11 is directed to "a needle

coupled to a thermally conductive heating element, wherein the heating element is coupled to a balanced circuit having two resistive circuit elements.” According to the Application, a balanced circuit is capable of measuring heat dissipation characteristics of a tissue environment in which the heating element is disposed. Thus, independent claims 1 and 11 contemplate an apparatus for determining injection depth and/or tissue type based on the heat dissipation characteristics of body tissue. (App., p.2, lns. 9-11)

In contrast, *Tay* discloses an apparatus for closing and sealing a puncture at a puncture site in a vessel located beneath the skin using radio frequency or other energy to cauterize the puncture. (col. 2, lns. 45-47) *Lull* discloses a sensor that includes a first resistor, a second resistor, a first circuit, and a second circuit wherein the first and second resistors each has a resistance that varies in response to a change in a physical property. (Abstract) According to *Lull*, the sensor can be applied in semiconductor manufacturing processes and automotive applications. (col. 17, lns. 1-5) There is no suggestion in the cited references that it is desirable to combine a sensor which, according to *Lull*, can be used in semiconductor manufacturing processes and automotive applications with a vessel cauterizing medical device, as taught by *Tay*. The statement made by the Examiner that it would have been obvious to modify *Tay* in view of *Lull* “in order to compare variations in the resistance of the heating element” is merely a characteristic of the sensor described in *Lull* and is not a proper motivation to combine the cited references. (Office Action, p.4-5)

Moreover, the fact that a claimed invention is within the capabilities of one of ordinary skill in the art is not sufficient by itself to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. MPEP 2143.01. In response to Applicant’s previous arguments that a proper motivation to combine was not set forth, the Examiner states: “*Tay et al.* fails to disclose any specific circuitry to control the anemometer. As a result, one having ordinary skill in the art would look towards the prior art for a circuit to control an anemometer.” (Office Action, p.6) The Examiner has provided no objective reason to combine *Tay* with *Lull*, but has merely made a generic statement that “one having ordinary skill in the art would look towards the prior art for a circuit to control an anemometer.” The Examiner has not met his burden in providing a proper motivation to combine the cited references.

Furthermore, Applicant asserts that the Examiner has improperly combined the references because *Tay* teaches away from the claims. MPEP 2145(X)(D). A prior art reference must be considered in its entirety including portions that lead away from the claimed invention. MPEP 2141.02(VI). Independent claim 1 includes the limitation of “a needle having . . . a distal portion suitable for *insertion* into tissue . . . and a lumen extending from a proximal end to the distal opening and in communication with the distal opening to allow a substance to be delivered through the lumen and out of the opening.” Independent claim 11 includes the limitation of “a needle having dimensions suitable for insertion into a body, and having a distal end capable of *puncturing* skin.” Thus, the needle in Applicant’s invention is either inserted into or punctures skin. By contrast, the cautery apparatus in *Tay* is designed to seal an already existing puncture wound in a vessel. (col. 5, lns. 10-62) Representatively, *Tay* discloses that the “present invention effects the hemostatic closure of a percutaneous or other type of puncture, incision or opening in a body vessel.” (col. 5, lns. 45-57) Thus, *Tay* teaches away from independent claims 1 and 11 and therefore was improperly combined with *Lull*.

B.

Claims 4 and 13 were rejected under 35 U.S.C. § 103(a) as being obvious over *Tay* in view of *Lull* in further view of U.S. Patent No. 3,740,604 to Zenick (“*Zenick*”). Dependent claim 4 depends from dependent claim 2 which depends from independent claim 1. Dependent claim 13 depends from independent claim 11. Therefore, claims 4 and 13 include at least each and every limitation set forth in independent claims 1 and 11. Thus, in view of Applicant’s remarks set forth above with respect to independent claims 1 and 11, Applicant respectfully submits that dependent claims 4 and 13 are patentably allowable.

C.

Claims 10 and 18 were rejected under 35 U.S.C. § 103(a) as being obvious over *Tay* in view of *Lull* in further view of U.S. Patent No. 5,873,835 to Hastings et al. (“*Hastings*”). Dependent claim 10 depends from independent claim 1. Dependent claim 18 depends from dependent claim 14 which depends from independent claim 11. Therefore, claims 10 and 18 include at least each and every limitation set forth in independent claims 1 and 11. Thus, in view

of Applicant's remarks set forth above with respect to independent claims 1 and 11, Applicant respectfully submits that dependent claims 4 and 13 are patentably allowable.


CONCLUSION

In view of the foregoing, it is believed that all claims now pending, namely claims 1, 3-20 and 26, patentably define the subject invention over the prior art of record, and are in condition for allowance and such action is earnestly solicited at the earliest possible date. If the Examiner believes that a telephone conference would be useful in moving the application forward to allowance, the Examiner is encouraged to contact the undersigned at (310) 207-3800x766.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP

Dated: 6/29, 2006



Shelley M. Cobos Reg. No. 56,174

CERTIFICATE OF MAILING

12400 Wilshire Boulevard, Seventh Floor
Los Angeles, California 90025
(310) 207-3800

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage thereon in an envelope addressed to: Mail Stop Amendment, Commissioner of Patents, Post Office Box 1450, Alexandria, Virginia 22313-1450, on 6-29, 2006.



Melissa Stead 6-29, 2006